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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,089	05/30/2001	Charles A. Nicolette	GZ 2099.00	6783

7590

08/22/2003

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/22/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,089

Applicant(s)

Nicolette

Examiner

Ungar

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 30, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-9 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1. Claims 1-9 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Groups 1-57. Claims 1-3 are drawn to a composition comprising at least two immunogenic ligands selected from the group consisting of 6 immunogenic ligands, wherein said ligands are SEQ ID NOS 3, 5, 7, 9, 11, 13 classified in Class 530 subclass 300+. It is noted that the number of combination of ligands claimed is 57. The analysis to take into account each of the claimed combinations is $2^N - (N+1) = \# \text{ of combinations}$. Thus $2^6 - (6+1) = 64 - 7 = 57$. Applicant is required to elect a specific combination for examination. It is further noted, for Applicant's convenience, that **this is not a species election requirement** but rather a requirement for election of the specific group to be examined.

Groups 58-114. Claims 4-8 are drawn to a host cell/composition comprising a host cell that comprises at least two immunogenic ligands

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selected from the group consisting of 6 immunogenic ligands, wherein said ligands are SEQ ID NOS 3, 5, 7, 9, 11, 13 classified in Class 435 subclass 325+. It is noted that the number of combination of ligands claimed is 57. The analysis to take into account each of the claimed combinations is $2^N - (N+1) = \# \text{ of combinations}$. Thus $2^6 - (6+1) = 64-7 = 57$. Applicant is required to elect a specific combination for examination. It is further noted, for Applicant's convenience, that **this is not a species election requirement** but rather a requirement for election of the specific group to be examined.

Group 115- 171. Claim 9 is drawn to a method of inducing an immune response comprising delivering a peptide composition comprising two or more immunogenic ligands selected from the group consisting of 6 immunogenic ligands, wherein said ligands are SEQ ID NOS 3, 5, 7, 9, 11, 13 classified in Class 514 subclass 2+. It is noted that the number of combination of ligands claimed is 57. The analysis to take into account each of the claimed combinations is $2^N - (N+1) = \# \text{ of combinations}$. Thus $2^6 - (6+1) = 64-7 = 57$. Applicant is required to elect a specific combination for examination. It is further noted, for Applicant's convenience, that **this is not a species election requirement** but rather a requirement for election of the specific group to be examined.

Group 172- 228. Claim 9 is drawn to a method of inducing an immune response comprising delivering a composition comprising a host cell which comprises two or more immunogenic ligands selected from the group consisting of 6 immunogenic ligands, wherein said ligands are SEQ ID NOS

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3, 5, 7, 9, 11, 13 classified in Class 424 subclass 93.21. It is noted that the number of combination of ligands claimed is 57. The analysis to take into account each of the claimed combinations is $2^N - (N+1) = \#$ of combinations. Thus $2^6 - (6+1) = 64-7 = 57$. Applicant is required to elect a specific combination for examination. It is further noted, for Applicant's convenience, that **this is not a species election requirement** but rather a requirement for election of the specific group to be examined.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-114 as disclosed are biologically and chemically distinct, made by and used in different methods and are therefore distinct inventions.

Further, Inventions 1 through 57 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05©)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as each subcombination will produce an immune response against the native ligand, thus each subcombination has utility by itself. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for producing an immune response against the same native ligand and can be used in combination with others of the claimed

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combinations in order to produce an immune response against the same native ligand. Thus the claims are distinct as required by MPEP 806.05©).

Further, Inventions 58 through 114 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05©)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as each subcombination will produce an immune response against the native ligand, thus each subcombination has utility by itself. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for producing an immune response against the same native ligand and can be used in combination with others of the claimed combinations in order to produce an immune response against the same native ligand. Thus the claims are distinct as required by MPEP 806.05©).

Inventions 115-228 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Further, Inventions 115 through 171 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05©)). In the instant case, the

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patentability of the combination method does not rely necessarily and solely on the patentability of any one subcombination method as each subcombination method will produce an immune response against the native ligand, thus each subcombination method has utility by itself. Further, each of the subcombination methods has utility by itself because each of the subcombination methods are useful for producing an immune response against the same native ligand and can be used in combination methods with others of the claimed combination methods in order to produce an immune response against the same native ligand. Thus the claims are distinct as required by MPEP 806.05©).

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

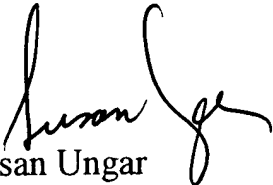
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Susan Ungar', with a stylized flourish at the end.

Susan Ungar
Primary Patent Examiner
August 21, 2003